DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 7-2-2008. Claims 1 & 18 have been amended. Claim 19 is newly added.

Applicant's comments directed to rejections applied in the previous Office Action are noted and deemed persuasive. Thus, those rejections have been withdrawn.

Claim Objections

Claim 1 is objected to because lines 1 & 2 recite the vasodilator active compound is applied to the condom's external surface and line 3 recite the vasodilator active compound is disposed on the condom's external surface. These limitations in claim 1 appear repetitive.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 8 recites the organic nitrate applied in a polar elastomer in solution, of which recitation is different from applicant's disclosure on page 3 lines 2-3.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
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> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 8-12, and 17-19 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Crosby et al (U.S. Patent No. 6,737,084). Crosby et al discloses a composition and methods for treating female sexual response.

With regards to claim 1, the Crosby et al reference discloses a composition comprises other active agents including vasodilators agents (column 5 lines 42-49), the composition administered to the exterior surface of a condom (column 5 lines 29-34).

With regards to claim 1 reciting the condom coated with a lubricant, lubrication incorporated in the condom or rubber sheath is well known in the art, evidenced by Clinch of U.S. Patent No. 3,136,417 (column 3 lines 59-63).

With regards to claim 1 reciting composition being immiscible with the lubricant, the Crosby et al reference teaches the composition can be carried by being impregnated within a sheath (column 5 lines 4-14), of which is well known to be the material for manufacturing condoms. With that in mind, since the composition impregnated within the condom's sheath, it will not be released from the condom, therefore the composition will not mix with any lubricant incorporated in the condom.

With regards to claim 2, the Crosby et al reference discloses the claimed invention except for the compound is disposed towards the open end of the condom. It would have been obvious to one having ordinary skill in the art at the time the invention was made to dispose it towards toe open end of the condom for purposes of being in the vicinity of the clitoris, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With regards to claim 3 reciting a carrier, the Crosby et al reference discloses the composition further comprises a carrier (column 5 lines 58-67 & column 6 lines 1-17), of which the carrier is pharmaceutically formulated with the composition (column 5 lines 59-67 & column 7 lines 1-18), rendering the two are miscible.

With regards to claim 8, the Crosby et al reference discloses the composition comprises phosphodiesterase (PDE) inhibitors (column 1 line 35-36).

With regards to claim 9, the Crosby et al reference discloses the composition comprises nitric oxide (column 1 lines 36-39).

With regards to claims 10, 12, 17, and 18 reciting the skin penetration enhancer, the Crosby et al reference the skin enhancer in the form of Azone (column 6 lines 39).

With regards to claim 11 reciting the skin penetration enhancer, the Crosby et al reference the skin enhancer in the form of Azone (column 6 lines 39).

With regards to claim 19 reciting the vasodilator active compound being immiscible in the lubricant, the Crosby et al reference discloses the composition comprises vasodilator agents (column 5 lines 42-49) and that the composition is immiscible with the lubricant, as established above, hence, the vasodilator agents would be immiscible with and in the lubricant.

Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084) and further in view of Moench et al (U.S. Patent No. 5,592,949).

Crosby et al, as presented above, discloses all elements recited in these claims including a lubricant but does not suggest the lubricant is buffered between 3 and 5 pH. Moench et al discloses an acidic buffered gel having a pH between 3 and 5 (column 12 lines 15-20) and this gel can also be used with a condom (column 15 lines 3-6). Therefore, it would have been obvious to one skilled in the art to utilize a lubricant buffered between 3 and 5 pH, as taught by Moench, as such would prevent hydrolysis of the active composition.

With regards to claim 13 reciting the skin penetration enhancer, the Crosby et al reference the skin enhancer in the form of Azone.

Claims 5-7 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084) and further in view of Osterberg (U.S. Patent No. 6,651,667) in view of Schwartz (U.S. Patent No. 5,626,149).

Crosby et al, presented above, discloses all elements recited in these claims except for the textured/undulating region to the external surface as recited in claim 5. The Osterberg reference discloses a male condom (10) comprising textured/undulating region on the external surface of the condom (10) in the form pockets (26). Therefore, it would have been obvious to one skilled in the art to modify the Crosby et al's condom to include texture/undulated region on the external surface of the condom in the form of pockets (26), as disclosed by Osterberg, for purposes of providing stimulation.

With regards to claim 6, the Osterberg's pockets (26) are filled with material (column 5 lines 23-28) but are not filled with a vasodilator medication therein. The Schwartz condom discloses fluid retaining chamber (4) storing therein. Therefore, it would have been obvious to one skilled in the art to modify the material in the Osterberg's pocket to now filled with the vasodilator medication therein, as taught by Schwartz for purposes of fulfilling a function, that is to release the medication upon a necessity.

With regards to claim 7, applicant's specification on page 2 (last paragraph) discloses the condom material formed of either natural rubber latex or a synthetic rubber-like material, of which material should be miscible with the vasodilator. With that in mind, the Osterberg reference discloses the condom (10) is manufactured of latex rubber but also can be manufactured from elastomeric materials such as urethane polymers, rubber, synthetic rubber, or non-allergic plastic (e.g. surgical plastic), see column 4 lines 7-11. Therefore, the Osterberg's

textured/undulating region is formed from latex rubber material, of which the same material condom is formed, which is miscible with the vasodilator, as disclosed by applicant's specification on page 2 (last paragraph).

With regards to claims 14-16 reciting the skin penetration enhancer, the Crosby et al reference the skin enhancer in the form of Azone (column 6 lines 39).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772